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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,529	06/14/2005	Masahiro Toda	38102-76017	2773

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EXAMINER

GAMETT, DANIEL C

ART UNIT	PAPER NUMBER
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1647

MAIL DATE	DELIVERY MODE
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11/30/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/509,529	Applicant(s) TODA ET AL.	
	Examiner Daniel C. Gamett, PhD	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 15 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14, 16 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>06/14/2004, 02/07/2007, 07/16/2007, 10/12/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election of claims 1-14, 16, and 17 in the reply filed on 09/28/2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 15 and 18 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 09/28/2007.
3. Claims 1-14, 16, and 17 are under consideration.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
5. Claims 1-14, 16, and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the independent claims 1 and 8 recites, "supernatant of the cell". The antecedent basis for "the cell" is unclear, as it is preceded by a neural stem cell, a dendritic cell, and a blood cell.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 8, 12, 14, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Hauben *et al.*, Lancet. 2000 Jan 22;355(9200):286-7 (of record). Hauben *et al.* administered autoimmune T cells to rats after spinal cord contusion (see whole document). The cells preparation taught in Hauben anticipates the “set” of instant claims 8 and 12, and the therapeutic agent of instant claim 14. Therefore the Hauben reference teaches the therapeutic administration of the composition comprising a blood cell as in instant claim 17.

8. Claims 1, 6-8, 11, 12, 14, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by WO/1997/009885 (March 20, 1997) (of record). WO/1997/009885 teaches methods in which allogeneic mononuclear phagocytes, including monocytes, macrophages and dendritic cells, are administered into the CNS at or near a site of injury or disease (page 3, line 28-page 4 line 2). Therefore, WO/1997/009885 teaches contacting of mononuclear phagocytes (a type of blood

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cell), including dendritic cells, with tissues that comprise neural stem cells. WO/1997/009885 further teaches a pharmaceutical composition comprising mononuclear phagocytes (see claim 18 in WO/1997/009885). “Dendritic cells” as taught in WO/1997/009885 necessarily include at least one of immature dendritic cells or mature dendritic cells, as recited in instant claim 6 and 11. These teachings anticipate the active steps of the instantly claimed methods and the recited components of the instantly claimed compositions because the instant claims merely recite different purposes and intended results for the methods and compositions. See *Bristol-Myers Squibb Co. v. Ben Venue Labs Inc.*, 246 F.3d 1368, 58 USPQ2d 1508 (Fed. Cir. 2001) (61 PTCJ 623, 4/27/01), where a patent for administering the anti-cancer drug paclitaxel was anticipated by a scientific article describing the same method but with no anti-tumor response. That court held that expressions of anti-tumor efficacy did not distinguish the claimed method from the prior art. The court further held that preamble language in claims of patents directed to administration of anticancer drug are expressions of purpose and intended result, and as such are non-limiting, since language does not result in manipulative difference in steps of claims. Therefore in the instant case, Applicant's assertions of an intended outcome and of a different result (“inducing proliferation of a neural stem cell” vs “promoting neural regeneration”) does not distinguish the claimed method over the prior art. Likewise, the instant recitation of “for a nerve injury” does not alter the nature of the instantly claimed compositions.

9. Claims 1, 8, 14, 16, and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6897060 (Bjornson), filed June 19, 1998. Bjornson teaches a composition comprising

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neural precursor cells in a physiological solution comprising granulocyte-macrophage colony-stimulating factor (GM-CSF) (see claim 1 in Bjornson). This composition anticipates the “set” of instant claim 8, and the therapeutic agent of instant claim 14. Merely putting the Bjornson composition together necessarily comprises contacting a neural stem cell with GM-CSF, as in instant claim 1. Bjornson further teaches therapeutic administration of the composition comprising GM-CSF (column 8, lines 55-60), as in instant claims 16 and 17. These teachings anticipate the active steps of the instantly claimed methods and the recited components of the instantly claimed compositions because the instant claims merely recite different purposes and intended results for the methods and compositions. Therefore, Applicant's assertions of an intended outcome and of a different result (“inducing proliferation of a neural stem cell” vs “generates hematopoietic cells”), does not distinguish the claimed method over the prior art. Likewise, the instant recitation of “for a nerve injury” does not alter the nature of the instantly claimed compositions.

10. Claims 1, 2, 5, 8, 14, 16, and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by US 20050244965 (Weiss), filed July 30, 2002. Weiss teaches a method comprising contacting multipotent neural stem cells with granulocyte-macrophage colony stimulating factor (GM-CSF), (see [0031] and claim 1). Teaching of this method is found in priority document 60399192, filed 07/30/2002. The method can be practiced in vitro and in vivo [0035] and may further include contacting the cells with EGF and/or FGF [0037]. Weiss teaches administration of both cells and GM-CSF for the treatment of demyelinating disease [0080-0085]. These teachings anticipate the active steps of the instantly claimed methods and the recited components of the instantly claimed

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compositions because the instant claims merely recite different purposes and intended results for the methods and compositions. Therefore in the instant case, Applicant's assertions of an intended outcome and of a different result (“inducing proliferation of a neural stem cell” vs “producing oligodendrocytes”) does not distinguish the claimed methods over the prior art. Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Conclusion

11. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel C. Gamett, PhD whose telephone number is 571 272 1853. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on 571 272 0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DCG

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30 November 2007

/David S Romeo/

Primary Examiner, Art Unit 1647